



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,461	09/29/2006	Wojciech Szczepiek	INFA-00101-NUS	9374
33794	7590	06/12/2008	EXAMINER	
MATTHIAS SCHOLL 14781 MEMORIAL DRIVE SUITE 1319 HOUSTON, TX 77079			JAISLE, CECILIA M	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			06/12/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTORECEIPT@GMAIL.COM  
IPRECEIPT@GMAIL.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,461	<b>Applicant(s)</b> WOJCIECH SZCZEPEK, ET AL.	
	<b>Examiner</b> CECILIA M. JAISLE	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 24-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09-29-2006 &amp; 08-24-2007</u> .                             | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED OFFICE ACTION**

### ***Lack of Unity***

Applicants' election of Group I, claims 1-13 and 24-32 with traverse in the Response of April 14, 2008 is acknowledged. Claims 14-23 are withdrawn as directed to non-elected subject matter.

Applicants traverse on the ground that the process of Claims 1-13 and 24-32 and the compound of claims 14-23 are commonly classified in the US classification system. However, a search both in the classification system and in the literature of a process as opposed to the final product has a distinctly different focus and goal. For this reason and all the reasons advanced in the Office Action of March 20, 2008, this Lack of Unity requirement is deemed sound and is maintained.

### ***Rejections Under 35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 and 24-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1: In step a), there is no antecedent basis for "the acid addition reaction." In step b), the recitation of "if necessary" fails to particularly point out and distinctly claim the intended subject matter, because conditions requiring such addition are undefined.

In the recitation of “the esters of lower carboxylic acids and C1-C4 aliphatic alcohols,” it is not possible to determine if the esters are of only the lower carboxylic acids or of both lower carboxylic acids and C1-C4 aliphatic alcohols. In addition, the moieties that would form such ester groups are undefined.

Claims 6, 7: The recitation of various percentages fails to define the process when there is no basis for the recited percentages (by weight, volume, mole, etc.).

Claim 8: The lack of antecedent basis for “the acid addition reaction” is noted above. The confusion regarding “the esters of lower carboxylic acids and C1-C4 aliphatic alcohols” is noted above.

Claims 10, 29: The reference to “boiling temperature” should indicate that it is of the reaction mixture itself.

Claims 11, 26, 30: The reference to “essentially free of the  $\beta$ -crystal form” fails to define the basis on which such purity is determined.

Claims 2-5, 9, 12, 13, 24, 25, 27, 28, 31, 32 are rejected as dependent on rejected claims.

### ***Allowable Subject Matter***

Claims 1-13 and 24-32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Following is an examiner's statement of reasons for allowance.

Claims 1-13 and 24-32 are unanticipated and unobvious over WO/1999/03854 in the stoichiometric ratio of the reactants. WO/1999/03854 does not describe or render obvious selective preparation of the  $\alpha$ -crystal form of imatinib methanesulfonate. In addition the claims are unanticipated and unobvious over all other prior art of record, whether taken individually or in any combination.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CECILIA M. JAISLE, J.D. whose telephone number is (571)272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**

CECILIA M. JAISLE, J.D.  
6/1/2008